

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3 -----

4 MYLAN PHARMACEUTICALS INC.,

5 Petitioner

6 v.

7 JANSSEN ONCOLOGY, INC.

8 Patent Owner

9 -----

10 Case IPR2016-01332

11 Patent No. 8,822,438

12 -----

13 VIDEOTAPED DEPOSITION OF EXPERT

14 IVAN T. HOFMANN, CPA/CFF, CLP

15

16 February 7, 2017

17 9:02 a.m.

18

19 700 13th Street NW

20 Washington, DC 20005

21

22 Denise D. Vickery, CRR/RMR

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1 A P P E A R A N C E S

2
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 22
 23 Also Present:
 24 Michael Gay, Videographer

1 I N D E X

2 EXAMINATION OF		
3 IVAN T. HOFMANN, CPA/CFF, CLP	PAGE	
4 BY MR. ZEGGER		5
5		
6 E X H I B I T S		
7 HOFMANN DEPOSITION EXHIBITS	PAGE	
8 JANSSEN 2006 January 26, 2016		86
9 Johnson & Johnson Reports		
10 2015 Fourth-Quarter Results		
11 JANSSEN 2007 January 24, 2017		88
12 Johnson & Johnson Reports		
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14 JANSSEN 2008 Concordia Pharmaceuticals v. 103		
15 Method Pharmaceuticals		
16 PREVIOUSLY MARKED EXHIBITS	REFERENCED	
17 MYLAN 1017 Declaration of		5
18 Ivan T. Hofmann, CPA/CFF, CLP		
19 MYLAN 1012 June 4, 2013 Response to		63
20 Office Action of March 4, 2013		
21 MYLAN 1055 Top 50 pharmaceutical		105
22 products by global sales 2014		
23		

1 P R O C E E D I N G S

2
 3 ---
 4 THE VIDEOGRAPHER: We are on the
 5 record. The time now is 9:02.
 6 This marks the beginning of disk
 7 No. 1 for the videotaped deposition
 8 testimony of Ivan Hofmann in the matter
 9 of Mylan Pharmaceuticals Inc. versus
 10 Janssen Oncology, Inc. This case is
 11 pending in United States Patent and
 12 Trademark Office before the Patent Trial
 13 and Appeal Board, case No. IPR
 14 2016-01332.
 15 Today's date is February 7, 2017.
 16 This deposition is being conducted at 700
 17 13th Street, Northwest, Washington, DC.
 18 Will all attorneys present please
 19 identify themselves and who they
 20 represent.
 21 MR. ZEGGER: My name is Paul
 22 Zegger. I'm with the firm of Sidley
 23 Austin for the Patent Owner, Janssen
 24 Oncology, Inc.
 MR. WHITE: I'm Brandon White

1 from Perkins Coie on behalf of the
 2 Petitioner.
 3 MS. STUBBINGS: Maria Stubbings
 4 from Perkins Coie also on behalf of
 5 Petitioner.
 6 THE VIDEOGRAPHER: My name is
 7 Michael Gay. I'm with Golkow
 8 Technologies. Our court reporter today
 9 is Denise Vickery also with Golkow
 10 Technologies and will now swear in our
 11 witness.
 12 ---
 13 IVAN T. HOFMANN, CPA/CFF, CLP
 14 called for examination, and, after having been
 15 duly sworn, was examined and testified as
 16 follows:
 17 THE VIDEOGRAPHER: You may
 18 proceed.
 19 EXAMINATION
 20 BY MR. ZEGGER:
 21 Q. Good morning.
 22 A. Good morning.
 23 Q. Let me show you Mylan Exhibit

Page 6	Page 8
<p>1 Sir, do you recognize this as 2 your declaration in the present IPR? 3 A. (Witness reviewing document). 4 I do. 5 Q. Is that your signature on page 6 24? 7 A. It is. 8 Q. Okay. You signed your 9 declaration back on June 30th of 2016? 10 A. Yes, sir. 11 Q. Is it correct that your 12 declaration deals with the issue of commercial 13 success as it relates to the issue of 14 obviousness or nonobviousness of the '438 15 patent? 16 A. It does. 17 Q. Okay. Do you have an advanced 18 degree in economics? 19 A. I have a bachelor's degree in 20 economics. 21 Q. Okay. Are you an oncologist? 22 A. I am not. 23 Q. Okay. Do you have any education 24 or background in the field of oncology?</p>	<p>1 is sometimes considered. 2 Q. How much time did you spend as of 3 the date of your declaration, June 30, 2016? 4 A. I don't have a firm number in 5 mind. 6 Q. Well, from the time that you were 7 first retained until the date of your 8 declaration, do you have some idea of the hours 9 that you've spent? 10 A. I would say dozens. Beyond that, 11 I can't refine it. 12 Q. All right. Did anyone help you? 13 A. Yes. 14 Q. Who? 15 A. In particular within my firm, 16 Raymond Bummer and Edward Lebair. 17 Q. What did they do? 18 A. So for projects such as this, I 19 identify a team to assist me. We basically 20 collaboratively review documents, evidence, 21 information, and develop what becomes my 22 declaration. So all their work is done under my 23 supervision and direction, but they assist me 24 in, you know, pulling together what ultimately</p>
<p>Page 7</p> <p>1 A. In terms of formal education, no. 2 I've studied issues involving pharmaceutical 3 economics in many fields, including oncological 4 products. 5 Q. Okay. Are you a urologist? 6 A. No, sir. 7 Q. Do you have any education or 8 background in the field of urology? 9 A. There again, no formal education, 10 but I've studied a variety of pharmaceutical 11 products that are directed to the field of 12 urology. 13 Q. Okay. You're a certified public 14 accountant; correct? 15 A. I am. 16 Q. Okay. When were you first 17 retained in connection with this IPR? 18 A. Sometime last May or June. 19 Q. What were you asked to do? 20 A. I was asked to consider the 21 economic issues surrounding claims of commercial 22 success and nexus with respect to the '438 23 patent in particular and obviousness inquiry</p>	<p>Page 9</p> <p>1 becomes the issued declaration. 2 Q. Did anyone else help you? 3 A. No. 4 Q. What criteria did you use to 5 determine commercial success? 6 A. Well, I think I explain my 7 opinions within my declaration. 8 The criteria as I understand it 9 or to look at the evidence that exists with 10 respect to the commercial performance of the 11 product and whether there's a nexus between the 12 commercial performance and the asserted claims 13 of the patent at issue. 14 Q. Do you have a particular metric 15 for the first part, the dollars part of the 16 commercial success analysis? 17 MR. WHITE: Objection to form. 18 THE WITNESS: I think there are a 19 number of different metrics that are 20 often looked at in a commercial success 21 inquiry directed to the question of 22 obviousness. 23 BY MR. ZEGGER:</p>

1 dollar metric that you use with respect to
2 commercial success?

3 MR. WHITE: Objection to form.

4 THE WITNESS: I don't believe
5 there are particular bright-line metrics
6 with respect to commercial success. It's
7 a very facts and circumstances intensive
8 inquiry.

9 BY MR. ZEGGER:

10 Q. Do you think Zytiga was a
11 commercial success?

12 A. My opinions are explained within
13 my declaration.

14 My opinion is that commercial
15 performance does not provide objective indicia
16 of nonobviousness in the form of commercial
17 success for the reasons outlined in my
18 declaration.

19 Q. Okay. One of those reasons was
20 lack of nexus; is that right?

21 A. Among others.

22 Q. Okay. Another reason was a
23 blocking patent; is that right?

24 A. Yes.

1 Q. Okay. But other than those, were
2 there any other reasons for your opinion that
3 there was no commercial success?

4 A. I think those are -- those are
5 central opinions, and I think the rest of my
6 opinions are laid out in my declaration.

7 Q. Okay. But your opinion is not
8 based on any lack of dollar sales of Zytiga; is
9 that right?

10 A. Well --

11 MR. WHITE: Objection. Form.

12 THE WITNESS: -- I think my
13 opinions are expressed in my report. I
14 provide, I think, context that's lacking
15 in the record as it exists with respect
16 to the findings of the examiner.

17 So I do, I think, provide context
18 to some of the claims with respect to the
19 commercial performance of Zytiga, but
20 ultimately my -- my opinions regarding
21 the lack of objective indicia of
22 nonobviousness tend to surround the
23 existence of the blocking patent and a

1 performance with the claims of the patent
2 at issue.

3 BY MR. ZEGGER:

4 Q. Well, let me put it this way.

5 If there were a nexus and there
6 weren't a blocking patent, would you have found
7 that there was commercial success in this case?

8 MR. WHITE: Objection to form.

9 THE WITNESS: Well, I think

10 that's a counterfactual hypothetical as I
11 understand to the landscape. So I think
12 there's a hazard in entertaining
13 counterfactual hypotheticals.

14 I think that very clearly there
15 is a blocking patent, very clearly there
16 is a lack of nexus. I don't -- I don't
17 quarrel with the fact that there are
18 relatively significant sales of Zytiga,
19 but in context that I provide.

20 So, you know, I think that the
21 opinions and conclusions with respect to
22 the lack of objective indicia are pretty
23 clearly laid out in my declaration.

24 BY MR. ZEGGER:

1 Q. Now, in Attachment A-1 of your
2 declaration, you have a list of materials that
3 you considered; is that right?

4 A. That's right, at least as of the
5 date of my declaration.

6 Q. Are all -- is that a complete
7 list of the materials that were provided to you
8 in connection with this IPR as of the date of
9 your declaration?

10 A. Yeah. As of the date of my
11 declaration, it's my attempt to administratively
12 gather the information. To the extent I cite
13 other things within the body of my declaration,
14 those would also be included.

15 Q. Were all of those materials
16 provided to you?

17 A. It would be some combination of
18 materials provided as well as, you know, things
19 I and my team pulled directly from the IPR
20 docket and/or independent research.

21 Q. On your list of materials
22 considered, can you identify those that you and
23 your team found on your own as opposed to being

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1 A. I can't as I sit here right now.
 2 Q. Could you look at your
 3 declaration, page 3, Footnote 1.
 4 Are you there?
 5 A. I am.
 6 Q. Okay. Now, that mentions a
 7 declaration of DeForest McDuff in an IPR brought
 8 by Amerigen; is that right?
 9 A. It does.
 10 Q. And your footnote states:
 11 "I have reviewed the McDuff
 12 declaration in forming my opinions."
 13 Is that right?
 14 A. Among other things.
 15 Q. Okay. Well, did you, in fact,
 16 review the McDuff December 4, 2015 declaration
 17 in IPR 2016-00286?
 18 A. I did.
 19 Q. Is it your understanding that
 20 Dr. McDuff is an economist who was hired by
 21 Amerigen in a different IPR?
 22 A. I think Amerigen as well as
 23 another petitioner.
 24 Q. Okay. Did you rely upon

Page 15

1 Dr. McDuff's declaration in forming opinions set
 2 forth in your declaration?
 3 MR. WHITE: Objection to form.
 4 THE WITNESS: I wouldn't say I
 5 relied upon it. I would say I reviewed
 6 it, and it was part of the information
 7 that I considered with respect to forming
 8 my opinions.
 9 BY MR. ZEGGER:
 10 Q. Did you talk to Dr. McDuff about
 11 his declaration?
 12 A. No, sir.
 13 Q. Did you copy portions of
 14 Dr. McDuff's declaration for use in your
 15 declaration?
 16 A. I certainly reviewed Dr. McDuff's
 17 declaration, and there are certain areas of my
 18 declaration where I followed the language that
 19 already existed as -- as one can see reviewing
 20 my declaration compared to his.
 21 Q. Well, have you compared your
 22 declaration to that of Dr. McDuff's to see if
 23 any portions are the same?

Page 16

1 Q. Well, would you be surprised if
 2 portions of your declaration are identical to
 3 those in Dr. McDuff's declaration?
 4 A. Not at all.
 5 Q. Okay. How many times have you
 6 performed financial and economic analyses
 7 relating to prescription pharmaceutical
 8 products?
 9 A. I mean, I've studied virtually
 10 every therapeutic class of drugs, clearly more
 11 than a hundred projects both in and outside of a
 12 dispute setting. I've studied pharmaceutical
 13 products and economic issues surrounding them.
 14 Q. Did any relate to cancer drugs?
 15 A. Yes.
 16 Q. How many?
 17 A. I haven't cataloged it
 18 specifically that way, but I would say dozens.
 19 Q. Well, did any of the cases you've
 20 worked on in the past relate to drugs to treat
 21 prostate cancer?
 22 A. Again, I haven't cataloged it
 23 that way. I'm sure they have.
 24 Q. Can you recall any matters that

Page 17

1 you've worked on relating to drugs to treat
 2 prostate cancer?
 3 MR. WHITE: And I just caution
 4 the witness to the extent anything is
 5 confidential about your prior engagements
 6 with clients, this transcript is public.
 7 So that's my caution.
 8 THE WITNESS: Yeah. Like I said,
 9 I haven't really cataloged it in the way
 10 you're asking it, and I am concerned
 11 because a lot of the work that I do is
 12 outside of a dispute setting and are
 13 confidential terms.
 14 So as I sit here right now, I'm
 15 not sure that I can get into projects or
 16 that able to provide specifics.
 17 BY MR. ZEGGER:
 18 Q. Well, I'm not asking you to
 19 divulge anything that would be of a confidential
 20 nature.
 21 I'm just asking whether any of
 22 your prior work has related to drugs to treat
 23 prostate cancer.

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